REPORT OF A GOOD LABORATORY PRACTICE (GLP)

AND BOOKS AND RECORDS

COMPLIANCE INSPECTION CONDUCTED

PURSUANT TO THE FIFRA REGULATIONS

INVESTIGATION ID:	20143955340
LABORATORY:	MicroBioTest Division of Microbac Laboratories, Inc. 105 Carpenter Drive Sterling, VA 20164
RESPONSIBLE OFFICIAL:	Donna B. Suchmann
Contact person:	Jeanne M. Anderegg Jeanne.anderegg@microbac.com Tel. 703-925-0100 Fax 703-925-9366
DATES OF INSPECTION:	April 22 - 24, 2014
INSPECTION TEAM:	Francisca Liem Stephen Tomasino

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APPENDICES

SUMMARY

A FIFRA Good Laboratory Practices (GLP) inspection was conducted at MicroBioTest, a division of Microbac Laboratories, Inc. on April 22 – 24, 2014. Three studies (Appendix B, C and D) previously submitted to the United States Environmental Protection Agency (EPA) were audited for compliance with FIFRA GLP regulations, data quality, validity and integrity.

The ***data audits*** revealed the following:

I. AOAC Germicidal Spray Test: Methicillin Resistant *Staphylococcus aureus* for product Maquat CA-6. EPA MRID No. 490164-21. Lab. Study No. 362-253.

1. Standard Operating Procedure for the AOAC Germicidal Spray Test (AOAC Method 961.02) was not available.
2. The Study Protocol lacks specificity and serves only as a template for the study. The Study Protocol does not identify a Standard Operating Procedure and contains outdated references to the test method. Test method SOPs should be based on the most current version of the standard methods.
3. No modifications to the SOP or AOAC standard method listed to accommodate testing of methicillin resistant *Staphylococcus aureus*.
4. Carrier transfer record only notes transfer time of 1 carrier; contact time for each carrier (10) must be documented in order to reconstruct the study.
5. Test microbe transfer log contained entries for multiple microbes, but they we not listed separately. The transfer logs must clearly delineate the transfer of each microbe, separately.
6. Media preparation log did not identify a source of the recipe of media preparation sheet, i.e., it was not possible to confirm if the media was being prepared correctly according to a Microbiotest procedure.
7. The Final Report does not contain the specificity necessary to fully understand how the study was conducted; thus, more detailed information should be provided.
8. Training files were deficient; personnel training was not based on a Microbiotest procedure (SOP) or standard method.
9. The study initiation date is confusing as it appear to be based on the signing of a "project sheet" rather than the study protocol.
10. Use of footnotes was common on the paperwork and led to confusing entries; use of multiple footnotes is discouraged.
11. The study director does not use the GLP definition of test substance. The test substance is called test agent or test article by the study director.
12. The GLP compliance statement was not signed by the sponsor and submitter.

II. Virucidal Hard Surface Test – Adenovirus Type 2; for product Maquat CA-6. EPA MRID No. 490164-14. Lab. Study No. 362-244.

1. A Standard Operating Procedure for the virus test method was not available to support the conduct of the study. Further, the documentation (study protocol, final report were generally vague and non-specific, thus reconstruction of the study was problematic.) (40 CFR 160.81, 40 CFR 160.120 and 40 CFR 160.185).
2. Version of ASTM Standard E1053 was not provided in study protocol. [40 CFR.160.120(a)(8)].
3. The Study Protocol lacks specificity and serves only as a template for the study. For example, it appears Sephacryl columns were used to aid in the neutralization process. However, it could not be ascertained whether this took place. [40 CFR 160.120(b)].
4. The Study Protocol does not identify a Standard Operating Procedure. Test method SOPs should be based on the most current version of the standard methods. [40 CFR.160.120(a)(8)].
5. Source of the 5% organic soil load not clearly identified (i.e., what it is and where it was added). [40 CFR.160.120(a)(8)].
6. Sponsor was not notified of a protocol deviation. The Study director signed a sponsor approved protocol. Any changes to the approved protocol should be approved by the sponsor. (40 CFR 160.120)
7. The Final Report does not contain the specificity necessary to fully understand how the study was conducted; thus, more detailed information should be provided. (40 CFR 160.185).
8. Tables in final report were not clearly identified or labelled. (40 CFR 160.185)
9. The GLP compliance statement was not signed by the sponsor and submitter (40 CFR 160.12).

III. Sanitizer Test for Non-Food Contact Surfaces using *Staphylococcus aureus* and *Enterobacter aerogenes*; for product Maquat CA-6. EPA MRID No. 490164-36. Lab. Study No. 362-265.

1. A Standard Operating Procedure for the sanitizer test method was not available to support the conduct of the study. (40 CFR 160.81).
2. The documentation (study protocol, final report) were generally vague and non-specific, thus reconstruction of the study was problematic. (40 CFR 160. 120 and 40 CFR 160.185).
3. The GLP compliance statement was not signed by the sponsor and submitter (40 CFR 160.12).
4. Sponsor was not notified of a protocol deviation. The Study director signed a sponsor approved protocol. Any changes to the approved protocol should be approved by the sponsor. (40 CFR 160.120).

I. INTRODUCTION

A FIFRA Good Laboratory Practices (GLP) compliance inspection was conducted at MicroBioTest, a division of Microbac Laboratories, Inc. on April 22 – 24, 2014. Three studies (Appendix B, C and D) previously submitted to the United States Environmental Protection Agency (EPA) were audited for compliance with FIFRA GLP regulations, data quality, validity and integrity. Ms. Jeanne Anderegg, Quality Assurance Manager was initially notified of the pending inspection via letter from Francisca Liem, Director, GLP Program (Exhibit 1). The letter identified the inspector, the studies to be audited, and the data and records to be made available.

II. OPENING CONFERENCE

An opening conference was held on Tuesday, April 22, 2014. The inspection was conducted by Francisca Liem, Director, GLP Program and Dr. Stephen Tomasino, Senior Scientist of the Office of Pesticide Programs Official credentials (Francisca Liem) and Letter of Authorization (Stephen Tomasino) (Exhibit 2) were presented to Ms. Angela Hollingsworth, representing Ms. Donna Suchmann (General Manager of MicroBioTest) and a FIFRA Notice of Inspection (Exhibit 3) was signed by Ms. Angela Hollingsworth. Exhibit 4 shows MicroBioTest staff who were present at the Opening Conference. Ms. Liem informed Ms. Hollingsworth that the inspection was routine and no violations were suspected. MicroBioTest has been inspected for GLP compliance on a number of occasions. Findings of the previous inspection were discussed. Not all previous GLP deviations were corrected. These deviations were noted in this inspection.

There were no changes in the structure and management of MicroBiotest. Details for the conduct of the inspection were discussed and an inspection schedule was agreed upon.

III. EXIT CONFERENCE

The exit conference was held on April 24, 2014 to review the findings of the FIFRA GLP inspection. A receipt for samples form (Exhibit 5) was provided to Ms. Angela Hollingsworth for all documents obtained during the inspection. In addition, the inspector provided the facility an Inspection Observation form (Exhibit 6) indicating the GLP deviations observed during the inspection. Attendees at the Exit Conference are shown as Exhibit 7.

V. EXHIBITS

Exhibit 1	Notification Letter (4 pages)
Exhibit 2	Letter of Authorization – Stephen Tomasino
Exhibit 3	FIFRA Notice of Inspection (1 page)
Exhibit 4	List of Attendees at Opening Conference (1 page)
Exhibit 5	FIFRA Receipt for Samples (2 page)
Exhibit 6	Inspection Observations (4 pages)
Exhibit 7	List of Attendees at Exit Conference (1 page)

VI. SIGNATURE:

Inspector Name: Francisca E. Liem
Affiliation: Office of Compliance

Francisca E. Liem

January 14, 2015

Date